ORIGINAL ARTICLE

Diagnostic Accuracy of Sonomammography in Diagnosis of BIRADS 4 Suspicious Breast Lesions Keeping Histopathology as Gold Standard

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ABSTRACT

Objective: To assess the diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions taking histopathology as gold standard.

Design of the Study: It was a descriptive cross-sectional study.

Study Settings: This study was carried out at Department Of Diagnostic Radiology And Diagnostic Imaging Combined Military Hospital, Lahore from January 2017 to June 2017.

Material and Methods: A total of 190 patients of age 30-70 years, presenting with palpable breast lesions with BIRAD ≥4 undergoing biopsy under local anesthesia were included. Patients with already diagnosed with breast cancer and recurrent breast lesion were excluded. Then all patients were undergone USG by using a high-resolution unit (PLM703AT) with a linear array probe centered at 7, 5 MHz, along with mammography using mamomet 3000 NOVA SIEMENS, General Electric Medical Systems, Milwaukee. Patients were labeled as positive or negative. Sonomammography findings were correlated with histopathological findings.

Results of the Study: In 117 sonomammography positive patients, 107 (True Positive) had malignant breast lesions and 08 (False Positive) had benign on histopathology findings. Among, 75 sonomammography negative patients, 06 (False Negative) had malignant breast lesions on histopathology whereas 69 (True Negative) had benign lesions on histopathology. Overall sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions taking histopathology as gold standard was 94.69%, 89.61%, 93.04%, 92.0% and 92.63% respectively.

Conclusion: This study concluded that diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions is quite high.

Keywords: Breast lesions, malignant, sonomammography, sensitivity.

INTRODUCTION

A heterogeneous group of lesions formed in benign breast disease which formed in mammary epithelium or in some other mammary tissues. These breast lesions are also associated with vascular, traumatic or inflammatory pathologies. On diagnosis by physician most lesions are identified to be benign in nature.[1] In a research conducted in Pakistan 200 patients enrolled having breast lump in which 80% patients were benign and 20% malignant lesions as per finding of histopathogy.[2]

Women mostly visit the department of imaging with a palpable abnormality of breast. Still there is confusion about the correct sequence and level of imaging that is required.[3] The most observed a characteristic of breast carcinoma is a palpable breast mass. Though, the frequently observed clinical features are non-specific in its diagnosis. For diagnosis of these lesions biopsy is considered as a gold standard method but several biopsies for benign abnormalities of breast for a long time recognized as a severe problem. There is an adverse effect of too much biopsy on the women who experience them and also adverse effect on society. So for its diagnosis there is a need of cost effective and less invasive methods without suffered in pain and intrusive surgical biopsy.[5]

The major clinical problem of breast cancer is its non-invasive diagnosis. In probable malignancy cases imaging studies are beneficial to clear the level of malignancy and to confirm the non-palpable masses in the breast at a different place or in the opposite side of the breast.[6]

Before biopsy performed images are useful in personifying the type of the mass. For women in which breast masses is detected clinically, majority of the patients required the ultrasonic evaluations.

Among women having age ≥ 40 years diagnostic mammography is the first imaging modality of their choice, ultrasound is not necessary till its benign identification.[7] Many authors have found outcome of mammographic BI-RADS category III lesions and also reported its rate of malignancy which is less than 2%.

Radiological community accepted this malignancy rate.[8] MRI BI-RADS category III is not regularly used modality and the levels of compliance of patients with follow up of imaging is conventional. The number of cancer patients for benign lesions is detected on MRI is greater than detected lesions on mammography, particularly for definite BI-RADS descriptors.[9]

Berg et al. (2004) reported the sensitivity of sonomammography was 91.5% and specificity was to be 23%.[10] While, Kumar et al. (2016) reported that overall sensitivity of sonomammography was 94.25% and specificity was to be 96.2%.[11],

Rationale of this study was to assess the diagnostic accuracy of sonomammography in differentiation of BIRADS 4 suspicious breast lesions taking histopathology as gold standard. Ambiguous evidence has been observed

in literature. Moreover, no local evidence is present in this regard which can help in deciding whether to rely on sonomammography in maximum number of cases for breast lesions. This study will help to evaluate the diagnostic accuracy of sonomammography in local setting to avoid the need of invasive procedures including biopsy and surgery. Moreover, we will get local magnitude which in future we can use to implement the use of sonomammography especially in negative cases.

MATERIAL AND METHODS

The study was conducted after approval from hospital's ethical and research committee. Informed consent in written form was taken from enrolled patients after telling them the protocols of the study. It was a descriptive cross-sectional study carried out at Department Of Diagnostic Radiology And Diagnostic Imaging Combined Military Hospital, Lahore from January 2017 to June 2017. Total 190 cases sample size was calculated keeping 95% level of confidence and taking expected frequency of malignant lesion to be 20%[2] with USG sensitivity 91.5% with 7.5% margin of error and USG specificity 23%[10] with 6% margin of error taking histopathology as gold standard. 190 patients referred to Radiology Department, CMH Lahore fulfilling selection criteria were enrolled in the study. Written informed consent was taken. Females of age 30-70 years, presenting with palpable breast lesions with BIRAD ≥4 undergoing biopsy under local anesthesia were included in this study. Bilateral cases (mass on both sides), females already diagnosed with breast cancer on other side and present for diagnosis of current side breast lesion, females with recurrent breast lesion after surgery (on medical record). Demographic detail (name, age, anatomical side, duration of symptoms) were also noted. Then all patients were undergone USG by using a high-resolution unit (PLM703AT) with a linear array probe centered at 7, 5 MHz, along with mammography using mamomet 3000 NOVA SIEMENS, General Electric Medical Systems, Milwaukee. Patients were labeled as positive or negative (as per operational definition). All scans were performed by a senior sonologist having at least 4 years' residency experience with assistance of researcher. Then patients were undergone biopsy sampling and samples were sent to the histopathology department. Reports of the patients were checked and they were detected as either positive or negative. All this information was recorded through proforma (attached).

The collected data was entered and analyzed in computer software SPSS21. Age, BMI and duration of

symptoms were presented as mean±SD. Gender, anatomical side and Achilles tendinopathy (in USG and surgical findings) were presented as frequency and percentage. To determine the, specificity, sensitivity, NPV, PPV and accuracy of ultrasonography, 2x2 tables was made at post-stratification taking surgical findings as gold standard. Data was stratified for age, anatomical side, BMI, size of the lump and duration of symptoms.

STUDY RESULTS

The age range of patients was 30 to 70 y having mean age of 48.27 ± 10.19 y. Mostly patients 131 (68.95%) were in the middle age of 30 to 50 years. The disease mean duration was 6.31 ± 2.57 months. Mean lesion size was 6.31 ± 2.57 cm. Mean BMI of the patients was 28.97 ± 2.46 kg/m². According to anatomical side distribution of patients is given in Table 1.

Table 1:Demographics of the Patients

Parameter		Frequency	Percentage
Age (years)	30-50	131	68.95
	51-70	59	31.05
	Mean ± SD = 48.27 ± 10.19 years		
Duration of disease	≤ 6 month	112	58.95
	>6 month	78	41.05
	Mean ± SD = 6.31 ± 2.57 months		
Size of lump	≤ 3 cm	100	52.63
	>3 cm	90	47.37
	Mean ± SD = 3.32 ± 1.93 cm		
BMI (kg/m2)	≤ 27	51	26.84
	>27	139	73.16
Anatomical side	Right	114	60%
	Left	76	40%

Table 2: Diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions taking histopathology as gold standard

	Positive result on Histopathology	Negative result on Histopathology	P-value
Positive on sonomammography	107 (TP)*	08 (FP)***	0.0001
Negative on sonomammography	06 (FN)**	69 (TN)****	

*-TP=True positive **-FP=False positive ***-FN=False negative ****-TN=True negative

Table:3 Sensitivity, Specificity, Positive &Negative Predictive Value and Diagnostic Accuracy of sonomammography

Modality	Value
sensitivity	94%
specificity	89.61%
PPV	93.04%
NPV	92.0%
Accuracy	92.63%

Table 4: Sensitivity, Specificity, Positive &Negative Predictive Value and Diagnostic of stratified variables

	Sensitivity	Specificity	PPV	NPV	Diagnostic Accuracy
Age 30-50 years	94.81%	88.89%	82.41%	92.31%	92.37%
Age 51-70 years	94.44%	91.30%	99.44%	91.30%	93.22%
Disease ≤ 6 month	92.31%	97.23%	90.91%	89.13%	90.18%
Disease > 6 month	97.92%	93.33%	95.92%	96.55%	96.15%
Lesion ≤ 3 cm	96.72%	87.18%	92.19%	94.44%	93.0%
Lesion >3 cm	92.31%	92.11%	94.11%	89.74%	92.22%
Anatomical right side	94.31%	90.11%	93.12%	88.14%	91.32%
Anatomical left side	100%	92.86%	95.83%	100%	97.30%

Sonomammography helped in diagnosis of malignant lesions of breast in 115 (60.53%) patients. Malignant cases confirmed on histopathology were 113(59.47%) cases. In

117 patients positive on sonomammography 107 (True Positive) patients had malignancy of breast lesions and 8 (False Positive) patients had benign on findings of

histopathology. In 75 sonomammography negative patients, 06 patients (False Negative) had malignant lesions of breast on histopathology while 69 (True Negative) patients had benign lesions of breast on histopathology as shown in Table VI.

Overall positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, specificity and sensitivity of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions taking histopathology as gold standard was 94.69%, 89.61%, 93.04%, 92.0% and 92.63% respectively. Stratification of diagnostic accuracy with respect to age groups, duration of disease, size of lesion, anatomical side is shown in Table 4.

DISCUSSION

We have conducted this study to assess the diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions keeping histopathology as gold standard.

Overall positive predictive value (PPV) (93.04%), negative predictive value (NPV) (92.0%), diagnostic accuracy (92.63%), specificity (89.61%) and sensitivity (94.69%) of sonomammography in evaluation of BIRADS ≥4 suspected lesions of breast keeping histopathology as gold standard. One study reported that the sensitivity and specificity of sonomammography were 91.5% and 23%, respectively.[10] Another study stated that for sonomammography overall sensitivity and specificity were 94.25% and 96.2% respectively.[11]

This practice parameter (amendment 2014) has been created for the support medical practitioners performing ultrasound examination of a whole breast. These practice parameters recommend the use of sonomammography along with imaging for detecting in mammographically compact breast, in diagnosis of lumps on breast in lactating and pregnant women or in those women having age less than 30 years.

The additional use of sonomammography to mammography alone in diagnosis or screening had revealed to enhance the sensitivity in detection of cancer. In a study comparing the diagnostic performances of physical examinations, sonomammography, mammography, Kolb et al.[12] described that only sonomammography assist in detection of non-palpable invasive cancer 30 women out of 71 with percentage of 42% in which no other cancer were sensed using any other modality for screening.[12]

Moss et al.[13] reported that in evaluating the lesion either benign or malignant on sonomammography the sensitivity was 88.9% and specificity was 77.9% in symptomatic women.[13] Stavros et al.[14] in evaluating the solid nodules of breast either benign or malignant on sonomammography observed its sensitivity was 99.8% and specificity was 30.5%, PPV (42.1%) and NPV was (99.6%).[14] In a study by Srirambhatla et al. (2016)[15], sensitivity, specificity, PPV, NPV of sonomammography was 95%, 79%, 68% and 97% in the lesion identification.

In symptomatic woman sonomammography had the advantage of separating solid lesion and cystic lesions, thus decreasing the mammographic BIRADS score and avoiding a biopsy on follow up. The malignant lesion which was missed on mammography can be detected on sonomammography.[16]

Sonomammography has proven as an efficient adjuvant to mammography considering the facts that it is a quick and non-invasive procedure, easily available and economical. Although a definitive diagnosis is possible with non-invasive imaging procedures, it is recommended to perform a biopsy/fine needle aspiration cytology for most lesions in order to derive reliable results.[12,13] The overall sensitivity and specificity of sonomammography in another study, was found to be 93.55% and 78.95%, respectively.[17,18] Imaging-pathology correlation is integral in multidisciplinary team and in establishing concordance or disconcordance between imaging findings and pathologic results for appropriate management of patients with breast pathologies. It is the effective utilization of the available imaging modalities i.e. the use of Sonomammography which provides higher sensitivity and specificity for evaluating Breast lesions thus helping in accurate and early detection of Breast malignancies

CONCLUSION

This study concluded that diagnostic accuracy of sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions is quite high. So, we recommend that sonomammography in diagnosis of BIRADS ≥4 suspicious breast lesions should be used as a main screening tool for accurate and pre-operative screening and detection of breast lesions in specific patients to decrease morbidity and mortality of breast lesion patients.

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